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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,501	07/30/2001	Hans-Peter Krimmer	210740US0X	1206

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EXAMINER	
PATTERSON, CHARLES L JR	
ART UNIT	**PAPER NUMBER**
1652	13

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,501	KRIMMER ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The PTO-1449 submitted on 2/27/03 has a reference that does not identify the journal or date, Wohlfahrt, et al. It does have a number "XP-000991533)" which is completely meaningless to me and would be to one reading the instant application. A person reading a patent issued on the instant application would not know where to obtain this reference. This reference has been crossed out on the PTO-1449 until a citation and date is given for this reference. The copy of the reference is present so applicants need not send another one.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10 and 12-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

To start with, a new matter rejection is added to this rejection in view of applicants addition of "in the presence of at least one racemase selected from...a carbamoyl racemase" in claims 1 and 19. Applicants cite "page

6, lines 9 and page 5, lines 1-15" for support. The second of the cited passages states that "special preference is given, however, to a process in which there is used a so-called whole cell catalyst from a cell that has a cloned gene coding for a hydantoin racemase, a hydantoinase and an L- or D-specific carbamoylase". No mention is made of a "carbamoyl racemase" and the citation to "page 6, lines 9" does not support this. Therefore, the mention of "carbamoyl racemase" must be deleted from the instant claim.

As for the arguments concerning the original 35 USC 112 first paragraph rejection, supplicants first urge that the rejection is based on "the Office's contention that the skilled artisan would not possess the knowledge at the time of the present invention's filing date to clearly understand, interpret, and perform within the scope of the claimed invention...[and that] it is this exact lack of knowledge by the skilled artisan that the Office relies upon to support the obviousness rejection". The rejection was based on the fact that the invention "subject matter was not described in the specification in such a way to reasonably convey...that the inventors, at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains... to make and/or use the invention. To start with, as discussed in the previous rejection, the specification teaches the use of *E. coli* cells, not the enzymes of the instant claims. Secondly, just because the prior art teaches something that would make the instant claims obvious does not indicate the specification teaches how to make and/or use the invention or that one of skill in the art would believe upon a reading of the specification that applicants had possession of the claimed invention. The art rejection has now been dropped so this argument is moot.

Next it is argued that page 6, lines 4-13 teaches the conditions suitable for *in situ* racemization. As stated previously, all that is shown in the specification is on page 7 where it is taught that when a DL-allysine hydantoin is mixed with *E. coli* cells and left for 4 hours at 37°C, a yield of L-allysine acetal of >85% was obtained having an optical purity of >99%. The cited passage on page 6 is in the general portion of the specification and does not teach any results. As stated previously, *E. coli* JM109 (pOM22, pOM21) is not described in the specification. Applicant responds that JM109 is described in US application 60/157,427, however MPEP 608.01(p)(I)(A) states that essential matter may be incorporated only from U.S. Patents, U.S. Patent Publications or pending U.S. Patent applications. 60/157,427 was a provisional application filed 10/4/99 that expired 10/4/00, nearly one year before the instant application was filed. At any rate, it is not now pending. Applicant may incorporate anything that was in that patent application into the specification if they can show that it was in fact in the provisional application. Applicants have submitted WO 00/58499, which has 60/157,427 as a priority document but have not pointed out specifically where it is taught what JM109 (pOM22, pOM21) is and the examiner does not readily find this disclosure in the instant patent. This is not a disclosure of 60/157,427 but is merely a child of this application that includes 2 other provisional applications as priority. In reference to the disclosure on page 7, it is not even stated that the "DL-allysine hydantoin" is the hydantoin of formula II Page 1 and original claim 1 state that formula II is a hydantoin but do not state that it is a "DL-allysine hydantoin" is recited on page 7. If applicants can show that the structure is a "DL-allysine hydantoin" then the examiner will consider whether to consider the data disclosed on page 7 as relating to formula II.

Reference is then made to the fact that "the Office contends that the present application lacks written description and enablement for 'contacting the hydantoin with the two enzymes'" and cites page 5, lines 1-4 and the references cited in the 103 rejections. It is pointed out, as previously stated, that page 5 is a general recitation without any indication of results. As to the reference in the 103 rejection, they do not contain the present limitation of a racemase and the 103 rejection has been dropped.

It is pointed out that in the previous action it was stated that "[i]t is not understood what is meant by...'or of a N-carbamoyl amino acid" and this has not been addressed by applicant.

Applicants have disclosed on page 7 the results of an experiment with a particular *E. coli* cell strain that is not defined in the specification and is not readily determined from the patent submitted to show this. There are some general recitations on pages 3-6 with no results shown and it is not even clear that the "DL-allysine hydantoin" discussed on page 7 is the same as formula II.

The previous art rejections are dropped in view of applicants' arguments and the inclusion in claims 1 and 19 of hydantoin racemase.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final

action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
May 9, 2003